4/30/97 BJR

DEPARTMENT OF HEALTH & HUMAN SERVICES

M871N

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 29 1997

VIA FEDERAL EXPRESS

WARNING LETTER

Mr. Uwe Walter
President
Walter Graphtek GmbH
Herrenhaus Altfesenburg, D-23843
Bad Oldesloe, Germany

Dear Mr. Walter:

During an inspection of your firm located in Bad Oldesloe, Germany, on March 3-6, 1997, the Food and Drug Administration (FDA) investigator determined that your firm manufactures digital electroencephalography (EEG) devices. The PL-EEG systems are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated under section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices regulations, as prescribed by Title 21, Code of Federal Regulations (21 CFR), Part 820, as follows:

1. Failure to assure that specification changes shall be subject to controls as stringent as those applied to the original device, as required by 21 CFR 820.100(a)(2). For example, there are no documented procedures for the initiation, verification, validation, approval, implementation and documentation of device hardware and software changes.

2. Failure to conduct processing control operations in a manner designed to assure that the device conforms to applicable specifications, as required by 21 CFR 820.100(b)(2). For example, the "Preparation of production Papers" utilized to document assembly requirements of Order Number does not reflect all User Manual or software license requirements.

3. Failure of the device history record to demonstrate that the device is manufactured in accordance with the device master record, as required by 21 CFR 820.184. For example, device history records (DHRs) for PL-EEG "Reader" stations contain "Safety Declarations" for "Recorder" stations; the DHR for PL-Praxis serial number contains incomplete "End Test" documentation; the DHR for "Reader" station serial number documents an inaccurate Tower Housing serial number; the DHR regarding the PC component contained an inaccurate ID number.

4. Failure to perform planned and periodic audits in accordance with written procedures by appropriately trained individuals not having direct responsibility for the matters being audited, as required by 21 CFR 820.20(b). For example, Quality Assurance Audits scheduled for week 50 of 1996 as well as week numbers 2, 4, 6, & 8 of 1997 have not been conducted.

5. Failure of the quality assurance program to identify, recommend, or provide solutions for quality assurance problems and verify the implementation of such solutions, as required by 21 CFR 820.20(a)(3). For example, corrective actions regarding observations made during three of [redacted] completed Quality Assurance Audits have not been implemented. The cited audits were conducted on August 30, 1996 and October 28, 1996.

6. Failure of the quality assurance program to assure that all quality assurance checks are appropriate and adequate for their purpose and are performed correctly, as required by 21 CFR 820.20(a)(4). For example, the "Server" program contained within the GM 200 test system utilized to test PL-EEG "Reader" stations contains inaccurate upper limits; the "Safety Declaration" contained within Device History Records (DHRs) of PL-EEG Recording Stations utilized to document that electrical safety test requirements had been met contain inaccurate upper limits; and Reader Station serial number awaiting Electrical Safety Testing was observed without benefit of complete EMI shielding.

7. Failure to control environmental conditions, such as electrostatic discharge, to prevent adverse affects on the device's fitness for use and to provide proper conditions for each of the operations performed, as required by 21 CFR 820.46. For example, there is no documented evidence that ESD control systems are periodically inspected to verify that they function properly; PCB's were observed awaiting repair without the benefit of ESD protection.

8. Failure to routinely calibrate measurement equipment, to establish adequate calibration procedures, and to maintain adequate calibration records, as required by 21 CFR 820.61. For example, the GM 200 system is not routinely calibrated; calibration procedures do not require an assessment of product conformance to specifications when test equipment is demonstrated to be out of calibration; and calibration records of instruments calibrated in house do not document instrument performance prior to adjustment.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions.

We acknowledge that you have submitted a response dated April 2, 1997, concerning our investigator's observations noted on form FDA-483. We have reviewed your response and have concluded that it is inadequate for the following reasons: A corrective action plan and timetable have not been established for maintaining accurate device history records, establishing and implementing change control procedures, completion of quality audits, inspection of ESD control systems and several records were not translated into the English language.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pending application for premarket approval (PMA) will be approved and no premarket notification (section 510(k) will be found to be substantially equivalent for products manufactured at the facility in which the above GMP violations were found until the violations have been corrected.

Given the serious nature of these violations of the Act, all PL-EEG Electroencephlcgraphy Systems manufactured by Walter Graphtek GmbH, Bad Oldesloe, Germany and may be refused entry into the United States (U.S.) until these violations are corrected.

In order to remove the devices from this detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that the response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections have been verified, your products may resume entry into this country.

Please notify this office, in writing, within 15 working days of receipt of this letter of the specific steps you have taken, or intend to take, to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If the documentation is not in English, please provide an English translation to facilitate our review. Please address your response and any questions to:

Mr. Donald W. Serra
U.S. Food and Drug Administration
CDRH, Office of Compliance
Cardiovascular and Neurological Devices Branch
2098 Gaither Road
Rockville, Maryland 20850 U.S.A.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Mr. Serra at the above address or at (301) 594-4648 or FAX (301) 594-4672.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

Draft:DWS:4/23/97
Reviewed:KPS:4/24/97
Reviewed:GWO:4/24/97
Revised:DWS:4/25/97 KPS 4/25/97

cc:
HFA-224
HFC-135
HFC-170
HFC-230
HFC-240
HFI-35(Purged)
HFR-MA100
HFR-MA200
HFR-MA240(RRuff)
HFZ-300
HFZ-306
HFZ-340 (3)
HFZ-341 (CVNB, DSerra)

CFN: 9613892
Last Date of Inspection: April 22-26, 1996
Date ORA signed off: March 27, 1997
Date ITOB Concurred: April 4, 1997
OC Receipt Date: April 8, 1997
Compliance Status for COMSTAT: Not Acceptable

OC Track: 68473